20

25

30

49

CLAIMS

- 1. A method of diagnosing colorectal tumors in a subject, the method comprising the steps of:
 - (a) detecting an expression level of one or more marker genes in a specimen collected from a subject to be diagnosed, wherein the one or more marker genes is selected from the group consisting of the genes listed in Table 1 and the genes listed in Table 2; and
- (b) comparing the expression level of the one or more marker genes to that of a control, wherein high expression level of a marker gene from Table 1 or a low expression level of a marker gene from Table 2, as compared to control, is indicative of colorectal tumor.
- 2. The method of claim 1, wherein the expression level of the one or more marker genes is determined by following steps of:
 - (i) synthesizing aRNA or cDNA of the marker genes from a specimen;
 - (ii) hybridizing the aRNA or cDNA with probes for marker genes; and
 - (iii) detecting the hybridized aRNA or cDNA with the probes quantifying the amount of mRNA thereof.

3. The method of claim 2, wherein the probes are fixed on a DNA array.

- 4. A method of screening for a therapeutic agent useful in treating or preventing colorectal tumors, said method comprising the steps of:
 - (iv) contacting a candidate compound with a cell expressing one or more marker genes, wherein the one or more marker genes is selected from the group consisting of the genes listed in Table 1, Table 2, Table 3, and Table 4; and
 - (v) selecting a compound that reduces the expression level of one or more marker genes selected from Table 1, Table 3, and Table 4, as compared to a control, or enhances the expression of one or more marker genes selected from Table 2, as compared to a control.

10

20

25

- 5. A method of screening for a therapeutic agent useful in treating colorectal tumors, said method comprising the steps of:
 - (vi) administering a candidate compound to a test animal;
 - (vii) measuring the expression level of one or more marker genes in a biological sample from the test animal, wherein the one or more marker genes is selected from the group consisting of the genes listed in Table 1, Table 2, Table 3, and Table 4;
 - (viii) selecting a compound that reduces the expression level of one or more marker genes selected from Table 1, Table 3, and Table 4, as compared to a control, or enhances the expression of one or more marker genes selected from Table 2, as compared to a control.
- 6. A method of screening for a therapeutic agent useful in treating colorectal tumors, said method comprising the steps of:
 - contacting a candidate compound with a cell into which a vector comprising the transcriptional regulatory region of one or more marker genes and a reporter gene that is expressed under the control of the transcriptional regulatory region has been introduced, wherein the one or more marker genes are selected from the group consisting of the genes listed in Table 1, Table 2, Table 3, and Table 4;
 - (x) measuring the activity of said reporter gene; and
 - (xi) selecting a compound that reduces the expression level of said reporter gene when said marker gene is selected from Table 1, Table 3, and Table 4 or that enhances the expression level of said reporter gene when said marker gene is selected from Table 2, as compared to a control.
 - 7. A method of screening for a therapeutic agent useful in treating colorectal tumors, said method comprising the steps of:
 - (xii) contacting a candidate compound with a protein encoded by a marker gene, wherein the marker gene is selected from the group consisting of the genes listed in Table 1, Table 2, Table 3, and Table 4;

20

25

- (xiii) measuring the activity of said protein; and
- (xiv) selecting a compound that reduces the activity of said protein when said marker gene is selected from Table 1, Table 3, and Table 4 or that enhances the activity of said protein when said marker gene is selected from Table 2.
- 8. The method of any one of claims 4, 5, 6 and 7, wherein the marker gene is selected from the group consisting of the genes listed in Table 3, and wherein colorectal tumor is colorectal adenoma.
- 9. The method of any one of claims 4, 5, 6 and 7, wherein the marker gene is selected from the group consisting of the genes listed in Table 4, and wherein colorectal tumor is colorectal carcinoma.
- 10. A method for treating or preventing colorectal tumors, said method comprising the step of administering a compound that is obtained by the method according to any one of claims 4, 5, 6 and 7.
 - 11. A method for treating or preventing colorectal tumors in a subject, said method comprising the step of administering to the subject an antisense nucleic acids against a marker gene, wherein said marker gene is selected from the group consisting of the genes listed in Table 1, Table 3, and Table 4.
 - 12. A method for treating or preventing colorectal tumors in an subject, said method comprising the step of administering to the subject an antibody or fragment thereof that binds to a protein encoded by a marker gene, wherein said marker gene is selected from the group consisting of the genes listed in Table 1, Table 3, and Table 4.
 - 13. The method of claim 11 or 12, wherein said marker gene is selected from the group consisting of the genes listed in Table 3, and wherein colorectal tumor is colorectal adenoma.

20

- 14. The method of claim 11 or 12, wherein said marker gene is selected from the group consisting of the genes listed in Table 4, and wherein colorectal tumor is colorectal carcinoma.
- 5 15. A method of treating colorectal tumors in a subject, said method comprising the step of administering to the subject a protein encoded by a marker gene, wherein said marker gene is selected from the group consisting of genes listed in Table 2.
- 16. A method for vaccinating a subject against colorectal tumors, the method comprising
 the step of administering:
 - (a) a DNA corresponding to one or more marker genes selected from the group consisting of the genes listed in Table 1, Table 3, and Table 4.,
 - (b) a protein encoded by a marker gene, or
 - (c) an antigenic fragment of a protein encoded by a marker gene. either alone, or in combination.
 - 17. The method of claim 16, wherein said marker gene is selected from the group consisting of the genes listed in Table 3, and wherein colorectal tumor is colorectal adenoma.
 - 18. The method of claim 16, wherein said marker gene is selected from the group consisting of the genes listed in Table 4, and wherein colorectal tumor is colorectal carcinoma.
- 25 19. A vaccine composition for treating or preventing a colorectal tumor, wherein the vaccine composition comprises one or more components selected from the group consisting of:
 - (a) DNA corresponding to one or more marker genes selected from the group consisting of the genes listed in Table 1, Table 3, and Table 4.,
 - (b) a protein encoded by a marker gene, and
 - (c) an antigenic fragment of a protein encoded by a marker gene.

15

20

- 20. A method of diagnosing adenoma, the method comprising the steps of:
 - (a) detecting an expression level of one or more marker genes in a specimen collected from a subject to be diagnosed, wherein the one or more marker genes is selected from the group consisting of the genes listed in Table 3; and
 - (b)comparing the expression level of the one or more marker genes to that of a control, wherein high expression level of a marker gene selected from Table 3, as compared to the control, is indicative of adenoma.
- 10 21. A method of diagnosing carcinoma, the method comprising the steps of:
 - (a) detecting an expression level of one or more marker genes in a specimen collected from a subject to be diagnosed, wherein the one or more marker genes is selected from the group consisting of the genes listed in Table 4; and
 - (b)comparing the expression level of the one or more marker genes to that of a control, wherein high expression level of a marker gene selected from Table 4, as compared to the control, is indicative of carcinoma.
 - 22. A method of diagnosing adenoma and carcinoma, the method comprising the steps of:
 - (a) detecting an expression level of one or more marker genes in a specimen collected from a subject to be diagnosed, wherein the one or more marker genes is selected from the group consisting of the genes listed in Table 3 and Table 4; and
 - (b)comparing the expression level of the one or more marker genes to that of a control, wherein a high expression level of a marker gene selected from Table 3, as compared to the control, is indicative of adenoma, and wherein a high expression level of a marker gene selected from Table 4, as compared to the control, is indicative of carcinoma.
- 30 23. The method of claim 22, wherein the marker genes comprise all of the marker genes set forth in Table 3 and Table 4.

WO 2004/001072 PCT/JP2002/012760

54

24. The method of claim 23, wherein step (b) further comprises the steps of determining a function of the log ratios of the expression profiles over the selected genes comprising summing the weighted log ratios of the expression profiles over the selected genes, wherein the weight for each gene is a first value when the average log ratio is higher for carcinomas than for adenomas and a second value when the average log ratio is lower for carcinomas than for adenomas.